

REMARKS

Claims 23-46 were pending in this application when last examined. Claims 43-45 have been withdrawn. Claims 23, 28-36, 39-42 and 46 are currently amended and claims 24-25 have been canceled. Support for the amendments can be found in the specification and original claims. No new matter has been added.

CLAIM REJECTION - 35 USC §112, FIRST PARAGRAPH

At page 3, the Office Action rejects claims 35-42 under 35 USC §112, first paragraph, enablement requirement. Applicants respectfully traverse this rejection.

The Office Action acknowledges that the specification is enabling for treating a disease related to the reduction of cognitive function and to mental fatigue, but does not reasonably provide enablement for preventing a disease related to the reduction of cognitive function and to mental fatigue, or preventing deterioration of the speed of memory in people with decreased cognitive function.

Currently amended claims 35, 36 and 40 address this issue and remove the "preventing" feature from the claims. Thus, the specification reasonably enables the full scope of the present claims. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

CLAIM REJECTION - 35 USC §112, SECOND PARAGRAPH

At page 10, the Office Action rejects claim 28 under 35 USC §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Amended claim 28 addresses the issue noted in the Office Action and further clarifies the amount of *Ginkgo* flavone glycosides in the extract. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

CLAIM REJECTION - 35 USC §103

At page 10, the Office Action rejects claims 23-26, 29-40 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics (online document) in view of BOMBARDELLI (EPA 0275005).

At page 14, the Office Action rejects claims 23-41 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics and BOMBARDELLI, in view of LOEW (Wiener medizinische Wochenschrift (1946)).

At page 16, the Office Action rejects claims 23-26, 29-40, 42 and 46 under 35 USC §103(a) as being unpatentable over PhysioLogics and BOMBARDELLI, in view of KIM et al. (FASEB Journal (2003)).

Applicants respectfully traverse these rejections.

The Office Action takes the position that PhysioLogics teaches a composition comprising phospholipid complex that

contains 20% phosphatidylserine and *Ginkgo biloba* extract that is advertised to treat mild memory problems associated with aging. What the Office Action does not recognize, however, is that the PhysioLogics product "Phospatidylserine Complex with Ginkgo" is not a Ginkgo-phospholipid complex that is the subject matter of the present claims. The PhysioLogics product advertised in the document is merely a mixture of a *Ginkgo biloba* extract and a phospholipid complex, i.e., it is not Ginkgo complexed with phospholipids. This is an important distinction between the composition of the present claims and that of PhysioLogics and other products that may have been available in the prior art. The PhysioLogics product is not a Ginkgo-phospholipid complex as defined in the specification.

The ingredients listed in PhysioLogics includes Neuro-PS™ which is "phospholipid complex from soy lecithin". The phospholipid complex contains phosphatidylserine, phosphatidic acid, phosphatidylinositol, soy phospholipids & glycerides, phosphatidylcholine and phosphatidylethanolamine. (See, also document from Neuro PS website (<http://www.neurops.com>) in the Appendix. A second separately listed ingredient is *Ginkgo biloba* extract. The PhysioLogics compound is recognized for containing phosphatidylserine, which plays a role in neurotransmission and supports cognitive function, and containing *Ginkgo biloba*, which helps improve memory.

The presently claims are directed essentially to methods for enhancing cognitive function and alleviating mental fatigue, improving memory speed and memory quality, or treating disease related to reduced cognitive function and increased mental fatigue. The methods comprise administering Ginkgo complexed with phospholipid and/or phosphatidylserine. As described in the specification, Applicants unexpectedly found that a *Ginkgo biloba* extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided by the non-complexed extract (see, page 3, lines 16-20 of the International PCT application). As described in the specification, the Ginkgo-phosphatidylserine complex can be obtained from a reaction of the active ingredients of an extract of Ginkgo with a phospholipid containing 20% phosphatidylserine (see page 5, lines 10-14). The specification further details the preparation of a complex between the *Ginkgo biloba* and phosphatidylserine (see page 6, lines 14-21).

The formation of *Ginkgo* phospholipid complexes enables the preparation of new biologically active compositions. In fact, they possess physico-chemical and spectroscopic characteristics which are markedly different from those of the original components and as such they can be incorporated as active principals into pharmaceutical formulations. For example, Ginkgo shows a strong affinity for phospholipids, resulting in the

generation of bonds which markedly modify the physico-chemical and spectroscopic characteristics of these new molecules (see page 6, lines 22-29).

BOMBARDELLI describes compounds combining flavenoids with phospholipids. BOMBARDELLI discloses that flavenoids possess a number of recognized properties such as anti-inflammatory, antispasmodic, antihistaminic, vasodilatory and platelet antiaggregating. The flavenoids can be applied topically but flavenoids are also known to be poorly absorbed. Thus, BOMBARDELLI addresses this problem by preparing compounds by reacting a flavenoid in an aprotic solvent with a phospholipid to form a complex compound which is then isolated.

BOMBARDELLI fails to teach or suggest, however, that flavenoids would have any effect on the enhancing cognitive function or alleviating mental fatigue, or for improving memory speed and memory quality, or for treating any disease related to reduced cognitive function and increased mental fatigue, which is the featured subject matter of the present claims. Furthermore, BOMBARDELLI fails to recognize that a *Ginkgo biloba* extract complexed with phosphatidylserine has significant effects above the non-complexed extract.

The specification shows, in the cognitive assessment tests and results, that *Ginkgo biloba* extract complexed with phosphatidylserine has outstanding effectivity compared with other tested species (i.e. non-complexed Ginkgo or Ginkgo-

phosphatidylcholine complex), regarding Quality of Memory, Picture Recognition Accuracy, Speed of Memory, Timed Memory Tasks, and other tasks concerning attention (see page 16, line 16 to page 29, line 5, and Figures 1-6). Further support for the unexpectedly superior results of a Ginkgo-phosphatidylserine complex was provided in the Rule 132 Declaration of Ezio Bombardelli, already of record. See, Amendment dated May 29, 2009.

BOMBARDELLI, however, fails to teach or suggest to one of ordinary skill in the art to form a Ginkgo-phospholipid complex and use this complex in a method for enhancing cognitive function and alleviating mental fatigue, or any of the other methods recited in the present claims.

LOEW describes additional details regarding the components of a Ginkgo extract such as bilobalide and terpene lactones, as well as additional disclosure regarding acetylcholinesterase inhibitors in treating dementia. Like BOMBARDELLI, however, LOEW also fails to teach or suggest the unexpected results of a Ginkgo-phospholipid complex in a method for enhancing cognitive function and alleviating mental fatigue, or any of the other methods recited in the present claims.

KIM describes the health benefits from botanicals such as grape seed extract due to the anti-oxidant activity of polyphenols and proanthocyanidins. The Office Action relies on KIM for teaching the incorporation of grape seed extract in the

PhysioLogics composition for the enhancement of cognitive function. Again, KIM, like LOEW and BOMBARDELLI, fails to teach or suggest the unexpected results of a Gingko-phospholipid complex.

For at least these reasons, PHYSIOLOGICS, BOMBARDELLI LOEW and/or KIM, in any combination, fails to teach or suggest, and would not have rendered obvious the method of claim 23, claim 35, claim 36, and all of claims 26-34, 37-42, and 46 depending thereon. Claims 24 and 25 have been canceled. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Entry of the above amendments is earnestly solicited. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

☒ - Neuro PS Website Document